Dear IVAM Members,

Greetings and welcome to our spring newsletter! Many thanks for your continued support and engagement throughout the year and at the Annual Meeting reception. 2023 was another banner year for progress and activity around New Approach Methodologies—however you define them—whether we are talking about the SOT Annual Meeting, NAMs-related webinar attendance, or progress in the international regulatory arena.

IVAM continues to see an increase in Annual Meeting Session/CE proposals submitted to us for endorsement and nominations for awards. This is a great problem to have! It shows the enduring interest and ongoing work happening in *in vitro* science. We appreciate those who volunteer to serve on the Executive Committee and those that help review proposals *ad hoc* as well. It's such a fun part of the Specialty Section, and I encourage you to reach out if you want to help.

In 2023, IVAM held a fantastic webinar on "Advancements Within the Field of Predictive Immunotoxicity In Vitro Models for Chemical Safety". Many thanks to our speakers, George Papadopoulos from Takeda Pharmaceuticals and Victor Johnson from NIH/NIEHS. We also held a virtual mentoring session hosted by IVAM officers Samantha Faber and Kathryn Page. Find out more and view any materials on the IVAM website.

Suggestions for future webinars are welcome at the survey found from this QR code (or you can grab one of us at the Annual Meeting).

To suggest webinar topics, use this QR code

The reception in Nashville, TN in March 2023 broke attendance records again! We hope you enjoyed yourself, and we are looking forward to seeing everyone again in Salt Lake City. The reception will be March 12, 2024, from 6:00–7:30 PM in Hyatt Regency Salt Lake Ballroom C. Please join us and read on to see some of the sessions endorsed by IVAM, and/or related to *in vitro* and alternative methods happening in Salt Lake.

2023-2024

IVAM Officers

President

Kristie M. Sullivan

Past President

Kathryn E. Page

Vice President

Samantha C. Faber

Vice President-Elect

Shaun McCullough

Secretary/Treasurer

Sebastian Hoffmann

Councilors

Melissa M. Martin
Lauren Lewis

Postdoctoral Representative

Anna Kreutz

Graduate Student Representative

Lucie C. Ford

Finally, the Officers will be looking for your help over the next several months (both in-person and online) to help us define IVAM's scope. That is what, in IVAM's view, is an *in vitro* or alternative method? While this can be a tricky subject to cover, we agree it's time to address it, because we are getting more and more questions around the scope of the Section related to endorsement of session proposals and eligibility for annual awards. Therefore, we would like to kick off a process to gather feedback and thoughts from membership. Only after a robust discussion period and multiple opportunities for the

membership to weigh in will any decisions—which could include guidelines for awards and session proposals or a revision of IVAM's bylaws—occur. We hope you will join us either during the Annual Meeting reception or a *to-be-scheduled* online meeting to share your views.

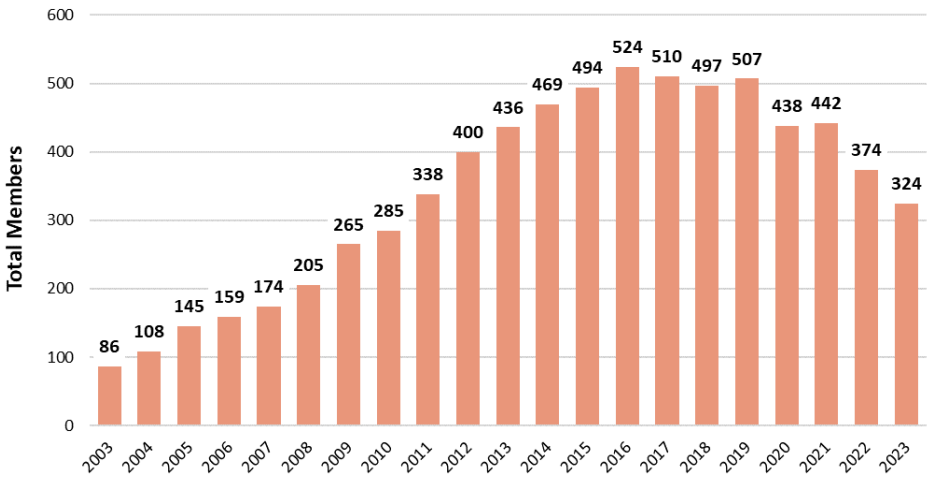
This newsletter contains information on IVAM membership, relevant publications, IVAM-related SOT activities, a featured topic, member spotlight, plus information specific to IVAM Postdoctoral and Graduate Student members. In addition, a new section highlighting some of the variety of careers in the IVAM membership sphere is included in "Career Corner", which aims to provide insight related to possible career trajectories and navigating career changes. Please check out the IVAM LinkedIn for future communications and to further engage with IVAM.

Sincerely,

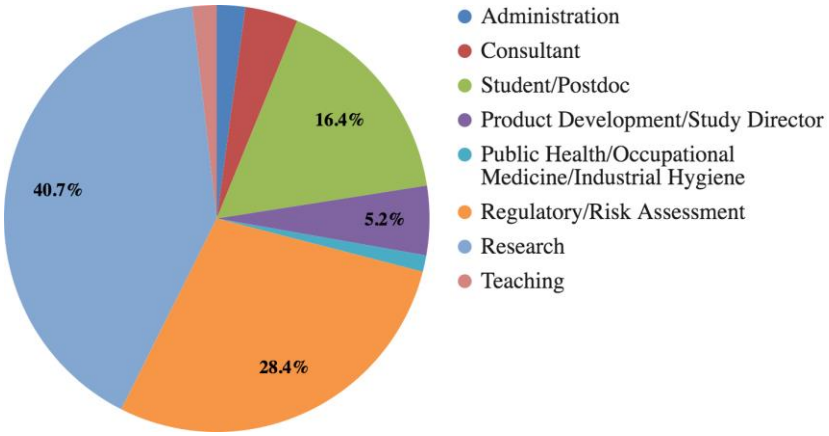
Kristie Sullivan, MPH
IVAM President, 2023-2024

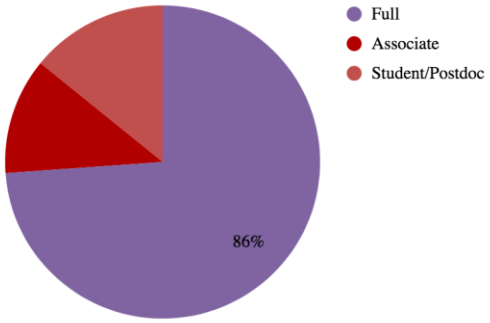
IVAM Announcements

Membership Update:



The IVAM Specialty Section was **founded in 1994** and grew steadily until 2016 when membership **peaked at 524**. As of January 2024, IVAM had **324 members**. Our members come from industry, academia, government, contract research organizations, and consulting. Over half are Full members and one-eighth are international members. The chart below provides a summary of IVAM membership.





2023-2024 Annual Report Highlights:

There were a variety of IVAM activities of note:

We reviewed 29 Session proposals submitted in May 2023 for SOT's 2023 Annual Meeting. Of these proposals, 16 were selected for the Annual Meeting. Of the 16 selected proposals, IVAM was the primary endorser for 7.

Over the last year, we sponsored two webinars:

1. We had an excellent turnout for our June webinar entitled, "Advancements Within the Field of Predictive Immunotoxicity *In Vitro* Models for Chemical Safety", organized by IVAM and the Immunotoxicology Specialty Section (ITSS). The field of *in vitro* immunotoxicity model development is driving more predictive first-in-human dosing and translatability of immune-mediated adverse events within the clinic. Our expert speakers (Drs. Vic Johnson (Burleson Research Technologies, Inc) and George Papadopoulos (Takeda Pharmaceuticals)) presented their current research surrounding *in vitro* immune model development and applications for drug development, and learnings from this webinar can be utilized for implementation of *in vitro* tiered screening and advancement of immune model development across research sectors.

2. This fall, IVAM hosted a virtual mentoring event tailored to students, postdocs, and early-career scientists interested in pursuing a career related to *in vitro* and alternative methods. We had over 20 mentors who volunteered their time for a small-group networking event. To ensure a broad scope of mentors, we included both early-stage and later-stage professionals from academia, consulting, government, non-profit organizations, and trade associations. They discussed their career paths and current positions. Mentees had the opportunity for one-on-one or small-group discussions with the mentors during the networking webinar. We are very grateful to the mentors for their time and to the mentees for participating. Thank you to everyone for their engagement and thoughtful discussions. We look forward to our next mentoring event!

Have your say: Upcoming Discussion on IVAM's Scope

We are looking to more clearly define the scope of IVAM as it applied to Session proposal endorsements and awards, and we want to make sure to get your input. We will therefore be bringing up this important topic at the SOT reception, as well as hosting a webinar following SOT. We will provide further details once we have them. We will also share a primer on this topic before the Annual Meeting, so watch your email for more information.

To suggest webinar topics, use this QR code

Award Recipients

In March 2023, we had another in-person SOT Annual Meeting, during which the IVAM graduate student and postdoctoral award winners were announced. The recipient of the Graduate Student Award was **Kyle Burns** from Oregon State University *(top left picture, pg 5)* and the recipient of both the Postdoctoral and MB Research Awards was **Dr. Alysha Simmons** from the University of North Carolina Chapel Hill (*top middle picture, pg 5)*. The IVAM Best Poster Award recipient was **Dr. Kimberley Rockley** from ApconiX, Alderley Park, UK *(right picture, pg 5)* and the Elsevier Best Poster Award recipient was **Dr. Ambra Madalon** from Università degli Studi di Milano (*bottom right, pg 5*). Finally, the Best Paper Award went to **Dr. Diane Ramsden** from Takeda Development Center Americas, now with AstraZeneca (*bottom left, pg 5).*

Kyle Burns: recipient of the Graduate Student Award

Dr. Alysha Simmons: recipient of the Postdoctoral & MB Research Awards

Dr. Kimberly Rockley: recipient of the Poster Award

Not Pictured

Dr. Diane Ramsden: recipient of the Best Paper Award

Dr. Ambra Madalon: recipient of the Elsevier Best Poster Award

Treasurer's Report

In March 2023, IVAM had a net asset of $25,389. As of November 2023, we have received $9,322 in membership dues, interest, and contributions. After expenses for the reception at SOT 2023, plaques, and graduate student and postdoctoral awards ($12,620 total), IVAM has a net asset of $22,091.

Welcome New IVAM Officers!

We're still awaiting election results—we hope to have them to announce for you at the SOT reception!

Featured Topic: A Brief History of the Developmental Neurotoxicity *In Vitro* Battery

Regulatory agencies worldwide rely on *in vivo* animal studies (e.g., US EPA OPPTS 870.6300 and OECD TG 426) for the assessment of potential developmental neurotoxicity (DNT) chemical hazard. These studies, however, have several limitations which may constrain efficient chemical screening. With enhanced concern around possible DNT and the long-lasting consequences, higher throughput *in vitro* strategies are imperative.

From the start, it was clear to researchers in *in vitro* developmental neurotoxicology that there was not a simple solution to model the complexity of the nervous system. Those in assay development, therefore, decided approaches that assessed fundamental neurodevelopmental processes were the best step forward in the evaluation of potential DNT chemical hazard. Not only would these approaches enhance chemical screening efficiency, but also potentially offer improved translation relative to traditional *in vivo* studies.

When I stepped into Bill Mundy's high-content imaging laboratory at the US EPA in 2009, I knew none of this. At the time, Bill and colleagues had recently published the first papers on two *in vitro* DNT assays, proliferation and neurite outgrowth. A limited number of chemicals had been screened in the assays, and the idea of an *in vitro* DNT battery seemed a distant future. Of course, me being a naïve undergraduate, I had no idea when Tim Shafer hired me to develop a combined proliferation and apoptosis assay in human neural progenitor cells that this would dramatically alter my future as well.

Although, I stepped away from *in vitro* DNT assay development in 2012 to attend graduate school, I could not have even imagined all the progress that would be made by the time I returned to the US EPA in 2019. By this point, the DNT *in vitro* battery (IVB), a collection of assays that measures fundamental neurodevelopmental processes, was established, and being evaluated by the OECD. The DNT IVB represented a decade plus long effort by three primary laboratories at the US EPA, University of Konstanz, and the Leibniz Institute for Environmental Medicine.

In July 2023, the numerous researchers involved in the development of the DNT IVB finally saw their hard work come to fruition when the Initial Recommendations on Evaluation of Data from the Developmental Neurotoxicity (DNT) *In Vitro* Testing Battery was published by the OECD. At this point, the assays were more readily accessible to other researchers like me, who hoped to validate and potentially improve upon these approaches. Further, the DNT community at large could also start to explore possible neurodevelopmental gaps not covered by an existing assay.

This brings us to today, as I step into my new role at the US FDA leading a group of scientists in implementing and applying the DNT IVB. It is the hope that many more researchers will answer the call to validate these approaches, and be able to demonstrate the reliability, efficiency, and translatability of the DNT IVB for the regulatory arena.

Megan Culbreth, PhD

Supervisory Toxicologist

Branch Chief Neurotoxicology and In vitro Toxicology

Division of Toxicology

OARSA I CFSAN I US FDA

Member Spotlight

IVAM would like to acknowledge members that have been recognized for outstanding achievements in 2022-2023. **Menghang Xia** from NIH/NCATS was awarded the SOT *Enhancement of Animal Welfare Award***.** The *Colgate-Palmolive Grant for Alternative Research* was awarded to **Erin Huber** from RTI International received the *Colgate-Palmolive Postdoctoral Fellowship Award in* In Vitro *Toxicology.* Congratulations on these outstanding achievements!

Graduate Student and Postdoctoral Corner

JOIN & GET INVOLVED! Trainees are essential to growth and maintenance of IVAM! The Specialty Section is committed to creating opportunities for success in all our research careers. As a member, trainees will have access to all these opportunities. Also, most trainees do not realize SOT waives the membership fee for the first Specialty Section or Special Interest Group you join. If you have questions or are interested in getting involved, please reach out to your graduate student or postdoctoral representatives!

Lucie Ford (Graduate Student representative)
lford@cvm.tamu.edu
Anna Kreutz (Postdoctoral representative)
anna.kreutz@inotivco.com

A Message to our fellow IVAM Graduate Student and Postdoctoral Members:

First and foremost, welcome to our new and returning IVAM Graduate Student and Postdoctoral members! We hope you have had a happy, healthy, and productive 2023-2024. Should you have any suggestions as to what we could incorporate here at IVAM to help connect you to the world of *in vitro* and alternative methods, please let us know!

We hope that you are finally adjusting to the scientific landscape in this post-pandemic world and enjoying taking advantage of the new virtual resources this has provided. We are excited that we were able to offer both a virtual mentoring event this past Fall, as well as help sponsor an in-person event at SOT this year. We hope to be able to host these events in subsequent years, so keep an eye out! Both virtual and in-person events have their own unique advantages, so we encourage you to take advantage of them however you are able! We hope that all IVAM Graduate Student and Postdoctoral members are able to attend SOT this year, as well as connect with us either at the IVAM Reception on March 12, 2024 or by stopping by our IVAM poster, which will be set up in the ToxExpo Hall.

Other SOT activities that might be of interest to graduate students and postdocs include luncheons, career-building workshops, posters, and Symposia; many of which will be either uploaded or recorded and can be viewed through the SOT Online Planner. Relevant sessions are listed below in the "SOT 2024 Annual Meeting" section of this newsletter. Also, please be on the lookout for an upcoming webinar for 2024. Remember to keep an eye out for events through the weekly SOT announcements or on our LinkedIn—we'd love to connect!

We wish you all the best in 2024-2025!!!

WELCOME TO THE IVAM CAREER CORNER!

A place to read about potential career options and trajectories in the field of toxicology. We also offer here information and advice that may be useful during times of career growth and transitions.

Current positions held by our officers:

Kristie Sullivan (President): Vice President, Education and Outreach (Institute for *In Vitro* Sciences)

Kathryn Page (Past President): Product Safety Toxicologist (The Clorox Company)

Samantha Faber (Vice President): Discovery Toxicologist (Takeda)

Shaun McCullough (Vice President-Elect): Senior Respiratory Scientist (RTI International)

Sebastian Hoffmann (Secretary-Treasurer): Independent Toxicology Consultancy (seh consulting + services)

Lauren Lewis (Councilor): Senior Scientist, Project Toxicologist (Bristol Myers Squibb)

Melissa Martin (Councilor): Regulatory toxicologist (BASF)

Anna Kreutz (Postdoctoral Representative): Senior Predictive Toxicologist (Inotiv)

Lucie Ford (Graduate Student Representative): Doctoral Student in the Interdisciplinary Faculty of Toxicology (Texas A&M University)

We also spoke with Katie Paul Friedman from the US EPA and asked her for some career-related advice.

Dr. Katie Paul Friedman is a Supervisory Toxicologist for the Computational Toxicology and Bioinformatics Branch in the Center for Computational Toxicology and Exposure in the Office of Research and Development at the US EPA. Her research focuses on the application of new approach methods to chemical safety assessment, with additional interests in variability in traditional toxicity information, endocrine bioactivity, and *in vitro* kinetics. She is a subject matter expert for the ToxCast program. Previously, Dr. Paul Friedman was a regulatory toxicologist at Bayer. She is active in multi-stakeholder projects to develop alternatives and their acceptance, including through technical leadership at Federal Advisory Committee reviews and in the consortium Accelerating the Pace of Chemical Risk Assessment. Her laboratory background includes development of high-throughput screening assays and combined use of *in vitro* and *in vivo* approaches. Dr. Paul Friedman received a PhD in Toxicology from the University of North Carolina at Chapel Hill and has authored more than 55 peer-reviewed publications and mentored more than 18 early-career trainees.

1. ***How did you find out about toxicology?***

In high school and college, I had a stay-in-school position at the US Environmental Protection Agency in Washington, DC. I knew I was interested in human health and the environment, but my first introduction to toxicology was in this work to support regulation of pesticides and toxic substances. Observing how regulatory toxicologists interacted with research toxicologists, I saw a conversation I wanted to join, but I wasn't quite sure where I fit in the conversation. My undergraduate research and major were focused on biochemistry and chemistry (and environmental policy and planning), and so it seemed that toxicology was applied biochemistry and chemistry for health questions.

2. ***What skills did you develop in your early career?***

Some advice I would give to trainees is to be open to developing your toolbox to chase down the problems in front of you, regardless of where you are in your career (skills of all kinds are needed at each level). My first US EPA job focused on populating a database and learning all of the acronyms and laws relevant to the US EPA to organize information. It was unclear to me at the time how databasing and knowing the framework of laws and regulations would help me in biochemistry research I was doing in the lab. Later, I learned to use *in vivo* models and biochemical toxicology, and then *in vitro* cell-based models; having the "traditional" and the "new approach methods" in my training helped me build bridges between them. In my postdoc years, I developed high-throughput screening assays (cell-based and cell-free). Then I had a data problem, where I needed more skills in structuring, curve-fitting, and analyzing these data, so I expanded my skills in R and MySQL because SAS and GraphPad were not the right tools to address the volume of the data. Then I moved to industry, and I learned about the problems and challenges in the agrochemical industry in using both traditional and new approach methods to evaluate chemical safety. With every new project has come the need to learn more discipline specific skills and analytical skills. I think through all of this, and in my current position since 2016, some of the most important skills I have learned are how to work with teams of people to accomplish something important together. Investing in people and relationships has been a profound and important part of my experience in toxicology, and has yielded unexpected, positive outcomes.

3. ***What is your favorite part about working in the field of toxicology?***

I love that toxicology is at the nexus of science (from many disciplines) and policy. I am challenged by continually learning from the disciplines and methods that we need to answer health questions within the context of regulations and laws. The analogy I think of often is that toxicology is to biochemistry (or many maybe sciences) as engineering is to physics; I enjoy the practical constraints on the work to design solutions to advance public health.

4. ***Best job negotiating tip?***

Interview at more than one place and get some competing offers! This will also help you understand what is reasonable in terms of an offer (in addition to what you might learn from doing some informational interviews with people in the field during your training). Interviewing is deep networking. My other "tip" is not really a negotiating tip, so much as a tip on how to make a choice. Sometimes, the job offers only a subset of: compensation/overall package, subject matter/work, opportunities for growth. If the job offers all 3, that's great! But some jobs might offer only 2 of 3. If you're down to 1 of 3, it's either not a good fit for you in this current phase of your life, or it's time to look for a job. What has helped me navigate between jobs (and sectors), and the difficulty of these decisions, has been keeping close to the type of work I wanted to be doing and ensuring I have opportunities to grow scientifically and professionally. I empathize with the sense of anxiety finding positions and then wondering if the position "closes a door" to some other position; but in my experience, if the work is guiding you between positions, you can build a unique path that might not look like someone else's trajectory.

5. ***What would you tell a trainee to help them prepare for an interview?***

Certainly be prepared to speak about your work now, and why you are interested in the work offered at the job opportunity. Make it easy for the interviewers to understand both your technical interests as well as your career interests, and how this position aligns with your views on how you want to develop yourself. Practically speaking, read some papers authored by members of the interview panel, google the company, etc. It will help you know more about the work they are doing, but your knowledge about the job may come through in your discussions.

IVAM Related Research 2023-2024

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SOT 2024 Annual Meeting

The SOT Annual Meeting will be held in Salt Lake City, UT March 10-14. Below, please find a curated list of talks, posters, workshops, and activities that may be of interest to IVAM members. Many of the posters were uploaded and Symposia were recorded, which can still be viewed. For the full meeting program, look here.

IVAM Relevant Activities:

Program legend: Continuing Education, Symposium/Platform Session, Workshop/Roundtable Session, Poster Session, Student/Postdoc Interest, Informational Session

IVAM Reception:

The IVAM Reception will be held on March 12th, 2024, from 6:00–7:30 PM MST in Salt Lake Ballroom C at the Hyatt Regency.

Sunday, March 10th

- 8:15 AM – 12:00 PM MST
  - AM05: Nix the Six: Strategies for Implementing Nonanimal Acute Toxicity Testing
  - AM07: Weight of Evidence Analysis and Problem Formulation for Chemical Risk Assessment Fundamental Principles and Application through Case Examples
- 1:15 PM – 5:00 PM MST
  - PM10: Harnessing Toxicology in Pregnancy: Traditional and Novel Approaches to Placental Toxicology Research
  - PM12: Putting Theory into Practice: Using Computational New Approach Methodologies in Next Generation Risk Assessment
  - PM13: Use of New Approach Methodologies of the Assessment of Inhaled Substances: Examples and Case Studies
- 7:30 PM – 9:00 PM MST
  - Student/Postdoctoral Scholar Mixer

Monday, March 11th

- 6:15 AM – 7:45 AM MST
  - SOT Mentoring Breakfast – Registration is required, space is limited
- 9:15 AM – 12 PM MST
  - Revolutionizing Detection and Prevention of Neurotoxic Effects: Harnessing the Power of in vitro and in Silico Approaches for Safer Drug Development and Environmental Monitoring
- 12:00 PM – 1:30 PM MST

- In Vitro Toxicology Lecture and Luncheon for Students: ToxAIcology-AI Will Only Replace Toxicologists Who Do Not Use It!
- 1:45 PM – 4:30 PM MST
  - On the Edge of the NAMs Frontier: Pioneering Efforts toward Intra- and Internationally Harmonized Regulatory Applications of New Approach Methodologies
  - Advances in New Approach Methods for Thyroid Toxicity Testing
  - Practical Applications of Machine Learning for Gaining Mechanistic Insights in Toxicology

Tuesday, March 12th

- 8:00 AM – 10:45 AM MST
  - State-of-the-Art in Vitro Immune Modeling: The Beginning of a Journey Towards AOPs and Improved Safety Assessment
- 11:00 AM – 12:30 PM MST
  - From Theory to Practice: Preparing Students for Careers in 21st-Century Toxicology
  - Placental Biology, Toxicology, and In Vitro Modeling for Predictive Developmental Toxicology
- 12:00 PM – 1:00 PM MST
  - Postdoctoral Assembly Luncheon
- 3:00 PM – 4:30 PM MST
  - In Vitro to In vivo Extrapolation to Predict Developmental Toxicity Potential
  - Applications of Annotations and Ontologies in Toxicology to Get Us on the Same Page for Maximizing Data Potential
- 4:45 PM - 6:05 PM MST
  - From My Cosmetics to Smart Watch, Toxicology Touches It All!
- 5:00 PM – 6:00 PM MST
  - Joint Mentoring Event (Medical Device and Combination Product Specialty Section, Risk Assessment Specialty Section, and In Vitro and Alternative Methods Specialty Section)

Wednesday, March 13th

- 8:00 AM – 10:45 AM MST
  - Human Cells as Nonanimal Alternative Approaches for Immunotoxicity Testing
  - Moving Stem Cell–Derived New Approach Methods toward Regulatory Acceptance
  - Advancements in Utilizing Zebrafish-Based Behavioral Assays for and Understanding Associated Cellular and Molecular Changes
  - Challenges and Future Perspectives on New Approach Methodologies Immunotoxicity Testing
- 11:00 AM – 12:20 PM MST
  - The Modernization of the Cosmetic Regulation Act: Perspectives on Recent Implementation Activities and Confirming Safety in Cosmetic Products
  - Is Less More? Reduction of Animal Use Through Virtual Control Groups
- 1:30 PM – 4:15 PM MST
  - Application of Early Molecular Measurements to Develop Points of Departure for Risk Assessment
- 6:00 PM – 7:30 PM MST
  - **IVAM Reception**

Thursday, March 14th

- 8:30 AM – 11:15 AM MST
  - Qualification of Complex in Vitro Models as Drug Development Tools: How Do We Translate Exciting Science into Regulatory Decisions?

In Vitro and Alternative Methods Specialty Section: relevant websites

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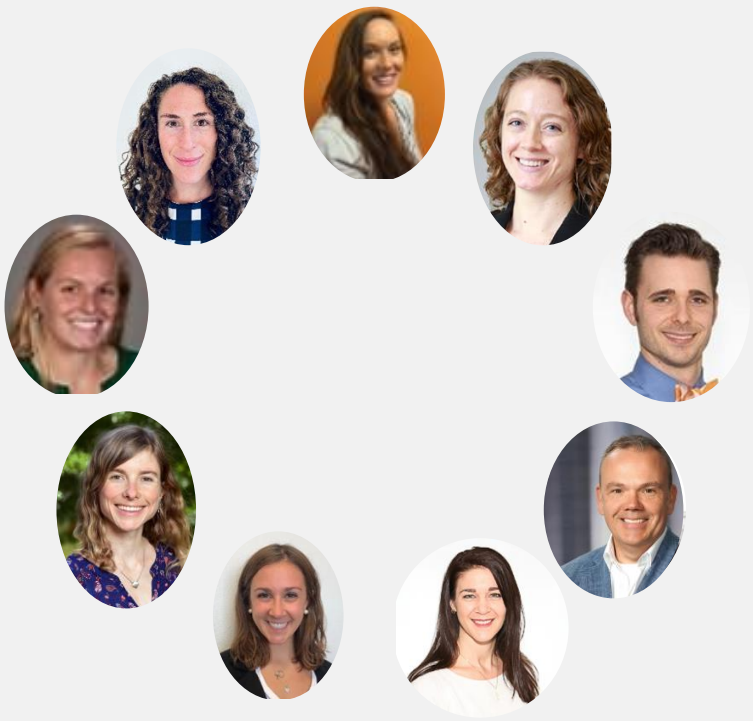
Applied *In Vitro* Toxicology	https://home.liebertpub.com/publications/applied-in-vitro-toxicology/626
Alternatives Research and Development Foundation	https://www.ardf-online.org
Alternatives to Animal Experimentation (ALTEX)	https://www.altex.org/index.php/altex
Alternatives to Laboratory Animals (ATLA)	https://frame.org.uk/what-we-do/atla-journal/
AltTox.org	http://alttox.org
Center for Alternatives to Animal Testing (CAAT)	https://caat.jhsph.edu
European Centre for Validation of Alternative Methods (ECVAM)	https://ec.europa.eu/jrc/en/eurl/ecvam
Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM)	https://ntp.niehs.nih.gov/whatwestudy/niceatm/iccvam/index.html
Japanese Center for Validation of Alternative Methods (JaCVAM)	https://www.jacvam.jp/en/index.html
NTP Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM)	https://ntp.niehs.nih.gov/whatwestudy/niceatm/index.html
Toxicology *In Vitro*	https://www.sciencedirect.com/journal/toxicology-in-vitro
Tracking System for Alternative Methods Towards Regulatory Acceptance (TSAR)	https://tsar.jrc.ec.europa.eu
Centre for Documentation and Evaluation of Alternative Methods to Animal Experiments (ZEBET)	https://www.bfr.bund.de/en/department_experimental_toxicology_and_zebet-53864.html

Sincere thanks to our 2022-2023 IVAM Officers



Clockwise from top: Kathryn Page *(Past President),* Kristie Sullivan *(President),* Shaun McCullough *(Vice President-Elect)*, Sebastian Hoffmann *(Secretary/Treasurer)*, Melissa Martin *(Councilor),* Lucie Ford *(Graduate Student Representative),* Anna Kreutz *(Postdoctoral Representative),* Lauren Lewis *(Councilor),* and Samantha Faber *(Vice President)*

Questions? Comments? Feedback? Want to get involved? Please feel free to reach out.

IVAM website IVAM LinkedIn